

JS-44 - CARD (Rev. 11/04)

## CIVIL COVER SHEET

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON PAGE TWO.)

## I. (a) PLAINTIFFS

LANCE T. RICE, a minor, by Michelle Rice, his mother and next friend, and by Eric J. Rice, his father and next friend, a resident of Indianapolis, Indiana

## (b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF (EXCEPT IN U.S. PLAINTIFF CASES)

Marion

## DEFENDANTS

BAYER CORPORATION, an Indiana corporation, successor to CUTLER BIOLOGICAL, a California corporation; BAXTER HEALTHCARE CORPORATION, a Delaware corporation, and its HYLAND DIVISION; and ALPHA THERAPEUTIC CORPORATION, a California corporation; ABMOIR PHARMACEUTICAL COMPANY, INC., a Delaware Corporation.

## COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT

(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

## ATTORNEYS IF KNOWN

E-filing

## II. BASIS OF JURISDICTION (PLACE AN "X" IN ONE BOX ONLY)

☐ U.S. Government Plaintiff

☐ Federal Question (U.S. Government Not a Party)

☐ U.S. Government Defendant

☒ Diversity (Indicate Citizenship of Parties in Item III)

## III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN "X" IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT)

(For diversity cases only)

Citizen of This State

☐ PTF ☐ DEF

Incorporated or Principal Place of Business in This State

☐ PTF ☒ DEF

Citizen of Another State

☒ 2 ☐ 3

Incorporated and Principal Place of Business in Another State

☐ 5 ☒ 6

Citizen or Subject of a Foreign Country

☐ 3 ☐ 5

Foreign Nation

☐ 6 ☐ 6

## IV. ORIGIN

(PLACE AN "X" IN ONE BOX ONLY)

☒ Original Proceeding

☐ Removed from State Court

☐ Remanded from Appellate Court

☐ Reinstated or Reopened

☐ Transferred from Another docket (Specify)

☐ Multistated Litigation

☐ Appeal to District Judge from Magistrate Judgment

## V. NATURE OF SUIT (PLACE AN "X" IN ONE BOX ONLY)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 119 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 121 Motor Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 161 Medicare Act <input type="checkbox"/> 162 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 163 Recovery of Overpayment of Veterans' Benefits <input type="checkbox"/> 168 Shareholders Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>PERSONAL INJURY</b> <input type="checkbox"/> 210 Airplane <input type="checkbox"/> 215 Airplane Product Liability <input type="checkbox"/> 220 Assault Libel & Slander <input type="checkbox"/> 230 Federal Employment Liability <input type="checkbox"/> 240 Marine <input type="checkbox"/> 245 Marine Product Liability <input type="checkbox"/> 250 Motor Vehicle <input type="checkbox"/> 255 Motor Vehicle Product Liability <input type="checkbox"/> 260 Other Personal Injury <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 270 Other Fraud <input type="checkbox"/> 271 Truth in Lending <input type="checkbox"/> 280 Other Personal Property Damage <input type="checkbox"/> 285 Property Damage Product Liability	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 RR & Truck <input type="checkbox"/> 650 Airline Haps <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 670 Other <b>LABOR</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt Relations <input type="checkbox"/> 730 Labor/Mgmt Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 750 Other Labor Litigation <input type="checkbox"/> 761 Emp./Ret. Inc. Security Act	<input type="checkbox"/> 820 Appeal 28 USC 188 <input type="checkbox"/> 825 Withdrawal 28 USC 187 <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 830 Copyrights <input type="checkbox"/> 835 Patent <input type="checkbox"/> 840 Trademark <b>SOCIAL SECURITY</b> <input type="checkbox"/> 845 SSA (1588F) <input type="checkbox"/> 850 Black Lung (330) <input type="checkbox"/> 855 DMCDWW (405(g)) <input type="checkbox"/> 860 SSD Title XVI <input type="checkbox"/> 865 TSP (405(g)) <b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (US Plaintiff or Defendant) <input type="checkbox"/> 871 IRS - Third Party 36 USC 7805	<input type="checkbox"/> 490 State Reapportionment <input type="checkbox"/> 495 Antitrust <input type="checkbox"/> 498 Banks and Banking <input type="checkbox"/> 499 Commerce/ICC Ratecases <input type="checkbox"/> 500 Deportation <input type="checkbox"/> 475 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 510 Selective Service <input type="checkbox"/> 520 Securities/Commodities/Exchange <input type="checkbox"/> 575 Customer Challenge 12 USC 3410 <input type="checkbox"/> 591 Agricultural Acts <input type="checkbox"/> 602 Economic Stabilization Act <input type="checkbox"/> 603 Environmental Matters <input type="checkbox"/> 604 Energy Allocation Act <input type="checkbox"/> 605 Freedom of Information Act <input type="checkbox"/> 606 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 607 Constitutionality of State Statutes <input type="checkbox"/> 608 Other Statutory Actions
<b>REAL PROPERTY</b> <input type="checkbox"/> 310 Land Condemnation <input type="checkbox"/> 320 Easements <input type="checkbox"/> 325 Rent Leases & Ejectment <input type="checkbox"/> 340 Torts to Land <input type="checkbox"/> 345 Tort Product Liability <input type="checkbox"/> 350 All Other Real Property	<b>CIVIL RIGHTS</b> <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 Other Civil Rights <input type="checkbox"/> 446 Amer. w/ Disab. - Emp. <input type="checkbox"/> 448 Amer. w/ Disab. - Other <input type="checkbox"/> 450 Consumer Credit <input type="checkbox"/> 455 Color/Teletext TV	<b>PRISONER PETITIONS</b> <input type="checkbox"/> 610 Motion to Vacate Sentence/ Habeas Corpus <input type="checkbox"/> 620 General <input type="checkbox"/> 625 Death Penalty <input type="checkbox"/> 640 Menteness & Other <input type="checkbox"/> 650 Civil Rights <input type="checkbox"/> 655 Prison Conditions		

## VI. CAUSE OF ACTION (CITE THE US CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE BRIEF STATEMENT OF CAUSE. DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY)

28 U.S.C. § 1332. This is a diversity action seeking damages for personal injuries caused by defective pharmaceutical product.

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION DEMAND \$ ☐ CHECK YES only if demanded in complaint UNDER F.R.C.P. 23 JURY DEMAND: ☒ YES ☐ NO

## VIII. RELATED CASE(S) IF ANY Gullone, et al. v. Bayer Corporation et al., No. 3:03-cv-02573-PJH, N.D. Cal., transferred to In re Factor VIII or IX Concentrate Blood Products Litigation, MDL No. 986 JFG, No. 1:93cv7452, N.D. Ill.

## IX. DIVISIONAL ASSIGNMENT (CIVIL L.R. 3-2)

(PLACE AN "X" IN ONE BOX ONLY)

☒ SAN FRANCISCO/OAKLAND☐ SAN JOSE

DATE

SIGNATURE OF ATTORNEY OF RECORD

5-21-07

Heather Foster

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JS-44 - CIVIL (Rev. 11/04)

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## COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT:

(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Robert J. Catron (State Bar No. 91112) Richard M. Gossens (State Bar No. 06107) Eleanor A. Foss (See the No. 291122) Michelle Donald (New York Bar No. 90797), L.L.P., CARRASCO, HERMAN & BERENSON, L.L.P., 275 Battery Street, 30th Floor, San Francisco, CA 94111, Tel: (415) 916-1000, Fax: (415) 916-2000; Lori J. Hume (New York Bar No. 21617), 275 Battery Street, 30th Floor, San Francisco, CA 94111 L.L.P. GROSS, L.L.P.

## ATTORNEYS (IF KNOWN)

E-filing

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☐ 1 U.S. Government Plaintiff

☐ 2 Federal Question (U.S. Government Not a Party)

☐ 3 U.S. Government Defendant

☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

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(For diversity cases only)

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PTF DEF

☐ 1

☐ 2 Incorporated or Principal Place of Business in This State

PTF DEF

☐ 2

☐ 3 Citizen of Another State

☒ 3

☐ 3 Incorporated and Principal Place of Business in Another State

☐ 3

☐ 4 Citizen or Subject of a Foreign Country

☐ 4

☐ 4 Foreign Nation

☐ 4

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VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION DEMAND \$ ☐ CHECK YES only if demanded in complaint; UNDER F.R.C.P. 23 JURY DEMAND: ☒ YES ☐ NOVIII. RELATED CASE(S) IF ANY *Gillies, et al. v. Bayer Corporation et al., No. 3:03-cv-02571-PJH, N.D. Cal., transferred to In re Factor VIII or IX Concentrate Blood Products Litigation, MDL No. 986 JFG, No. 1:92cv7452, N.D. Ill.*

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(PLACE AN "X" IN ONE BOX ONLY)

☒ SAN FRANCISCO/OAKLAND☐ SAN JOSE

DATE

SIGNATURE OF ATTORNEY OF RECORD

5-21-07

Heather Foster

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JS-44 Page 2  
(Rev. 11/64)INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS-44  
Authority For Civil Cover Sheet

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I. (a) Plaintiffs - Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant rule takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS-44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

V. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section IV above, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause.

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS-44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases. Date and Attorney Signature.

Date and Attorney Signature. Date and sign the civil cover sheet.

Elizabeth J. Cabraser (State Bar No. 83151, ecabraser@lchb.com)  
 Richard M. Heimann (State Bar No. 063607, rheimann@lchb.com)  
 Heather A. Foster (State Bar No. 184353, hfoster@lchb.com)  
 LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP  
 275 Battery Street, 30th Floor  
 San Francisco, CA 94111-3339  
 Telephone: (415) 956-1000  
 Facsimile: (415) 956-1008

Attorneys for Plaintiffs

\*Additional plaintiffs' counsel listed on signature page

UNITED STATES DISTRICT COURT  
 NORTHERN DISTRICT OF CALIFORNIA

LANCE T. RICE, a minor, by Michelle Rice, his mother  
 and next friend, and by Eric J. Rice, his father and next  
 friend, a resident of Indianapolis, Indiana

Plaintiff,

v.

BAYER CORPORATION, an Indiana corporation,  
 successor to CUTTER BIOLOGICAL, a California  
 Corporation; BAXTER HEALTHCARE  
 CORPORATION, a Delaware corporation, and its  
 HYLAND DIVISION; ARMOUR PHARMACEUTICAL  
 COMPANY, INC., a Delaware corporation and ALPHA  
 THERAPEUTIC CORPORATION, a California  
 corporation,

Defendants.

Case No.

2680

**COMPLAINT FOR  
 DAMAGES AND  
 INJUNCTIVE RELIEF**

Jury Trial Demanded

- (1) Negligence
- (2) Negligence Per Se
- (3) Fraudulent Omission and Concealment
- (4) Breach of Implied Warranty

**I. INTRODUCTION**

1. Defendants manufactured blood products known as "Factor VIII" and  
 "Factor IX" for the treatment of hemophilia, and sold these products to people with hemophilia in  
 the United States and worldwide, despite knowledge that the products were manufactured from  
 sick, high-risk donors and/or known to be contaminated with the virus that causes Non-A, Non-B  
 Hepatitis (now known as "Hepatitis C" or "HCV"). Defendants knowingly declined to timely  
 pursue or adopt treatment and manufacturing practices that would have prevented the infection of  
 Plaintiff with HCV, as described in more detail below. Defendants also continued selling old  
 stocks of products they knew to be contaminated with HCV even after they or others had

1 introduced safer products. Plaintiff is a person with hemophilia who contracted HCV through use  
2 of Defendants' contaminated products. This complaint describes the factual predicate for  
3 Plaintiff's infection: a pattern of foot-dragging, denial, and obfuscation by the pharmaceutical  
4 companies on whom his health and well-being depended.

5           2. Defendants manufactured HCV-contaminated blood factor products using  
6 human plasma taken from thousands of paid donors, including populations then known to be at  
7 high risk of carrying blood-borne diseases, such as urban homosexuals, prisoners, and intravenous  
8 drug users. Defendants intentionally recruited urban homosexuals who had a history of viral  
9 hepatitis as plasma donors, despite regulations prohibiting the use of such donors and despite  
10 knowledge that the virus that causes HCV was a blood-borne disease prevalent in such  
11 populations. Defendants continued using plasma taken from high-risk prison donors, even after  
12 promising the FDA that they would cease doing so. Through their trade associations, Defendants  
13 actively conspired to conceal these practices and to substantially delay product recalls and  
14 implementation of safety measures.

15           3. Defendants failed to fully and completely disclose the known risks of their  
16 products, including the risk of HCV; failed to implement readily available screening tests that  
17 would have prevented HCV by excluding contaminated plasma; failed to use available methods  
18 of treating plasma to kill viruses, including treatment with solvents and/or detergents; and  
19 concealed and affirmatively misrepresented the extent of the health dangers of the diseases caused  
20 by the products. Defendants also continued to sell old stocks of product that had not been treated  
21 even after introducing a safer treated product, including stocks that Defendants knew or had  
22 reason to know were made from pooled blood contaminated with HCV.

23           4. Defendants' efforts to maximize profits came at the expense of the health  
24 and lives of thousands of people with hemophilia in the United States and worldwide who were  
25 needlessly infected with HCV, including LANCE T. RICE.  
26  
27  
28



## II. JURISDICTION AND VENUE

5. Plaintiff alleges an amount in controversy in excess of \$75,000, exclusive of interest and costs. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendants.

6. Plaintiff is informed and believes and on such information and belief alleges that the conduct by Defendants that is relevant to the subject matter of this action took place primarily in their respective headquarters location and in other facilities within the States of California and Illinois, giving these states significant contacts to the claims asserted by Plaintiff and creating state interests such that the choice of either or each of these states' laws to govern the adjudication of this action is neither arbitrary nor fundamentally unfair.

## III. PARTIES

7. Plaintiff LANCE T. RICE, a minor, by Michelle Rice, his mother and next friend, and by Eric J. Rice, his father and next friend, a resident of Indianapolis, Indiana who has hemophilia. Plaintiff has already provided Defendant with a confidential Preliminary Patient Profile Form ("PPPF"), with beginning Bates number L-PPF 001136. The PPPF contains substantial additional information regarding Plaintiff's claim.

8. Plaintiff suffers from serious injuries and diseases, including HCV and associated symptoms, as a direct and proximate result of use of Defendants' blood products.

9. Plaintiff would not have chosen to be treated with Defendants' blood products had he known of or been informed by Defendants of the true risks of using those products or the nature of the sources of the products.

10. Defendant CUTTER BIOLOGICAL ("CUTTER"), the predecessor of Miles, Inc., and Defendant BAYER, was a California corporation headquartered in Berkeley, California at all pertinent times. At all pertinent times CUTTER and its successors Miles, Inc. and BAYER regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of factor concentrates produced from such plasma, to which Plaintiff was exposed and which contributed directly or indirectly to Plaintiff's infection with HCV.

1           11. Defendant BAYER CORPORATION ("BAYER"), formerly Miles, Inc., is  
2 and was an Indiana corporation, authorized to do business in all 50 states and the District of  
3 Columbia. Miles, Inc. had its principal place of business operation in Elkhart, Indiana, while its  
4 successor BAYER has its principal place of business in Pennsylvania, with offices located at 100  
5 BAYER Road, Pittsburgh, Pennsylvania 15205. At all pertinent times BAYER and its  
6 predecessors Miles, Inc., and CUTTER regularly and systematically engaged in the harvesting  
7 and collection of human plasma and the processing, manufacturing, marketing, sales and  
8 distribution of factor concentrates produced from such plasma, to which Plaintiff was exposed  
9 and which contributed directly or indirectly to Plaintiff's infection with HCV.

10           12. Defendant BAXTER HEALTHCARE CORPORATION ("BAXTER") is a  
11 Delaware corporation, authorized to do business in all 50 states and the District of Columbia, with  
12 its principal place of business in Illinois, with offices located at One Baxter Parkway, Deerfield,  
13 Illinois 60015. At all times pertinent, Defendant BAXTER, and/or its HYLAND DIVISION, had  
14 its main manufacturing plant in Glendale, California. At all times pertinent, Defendant  
15 BAXTER, and/or its HYLAND DIVISION, and/or its wholly owned subsidiaries Travenol  
16 Laboratories, regularly and systematically engaged in the harvesting and collection of human  
17 plasma and the processing, manufacturing, marketing, sale and distribution of FACTOR  
18 CONCENTRATE products produced from such plasma, to which Plaintiff was exposed and  
19 which contributed directly or indirectly to Plaintiff's infection with HCV.

20           13. Defendant ARMOUR PHARMACEUTICAL COMPANY, INC.  
21 ("ARMOUR") is a Delaware corporation, with its principal place of business in Pennsylvania,  
22 with offices located at 500 Arcola Road, P.O. Box 1200, Collegeville, Pennsylvania, 19426-0107.  
23 At all times pertinent, ARMOUR regularly and systematically engaged in the harvesting and  
24 collection of human plasma and the processing, manufacturing, marketing, sales and distribution  
25 of factor concentrate products produced from such plasma, to which Plaintiff was exposed and  
26 which contributed directly or indirectly to Plaintiff's infection with HCV.

1           14. Defendant ALPHA THERAPEUTIC CORPORATION ("ALPHA") is a  
 2 California corporation, with its principal place of business in California, with offices at 5555  
 3 Valley Boulevard, Los Angeles, California 90032. At all times pertinent, Defendant has been  
 4 regularly and systematically engaged in the harvesting and collection of human plasma, and the  
 5 processing, manufacturing, marketing, sale and distribution of factor concentrate products  
 6 produced from such plasma, to which Plaintiff was exposed and which contributed directly or  
 7 indirectly to Plaintiff's infection with HCV.

8           15. Defendants CUTTER, BAXTER, ARMOUR and ALPHA (hereinafter  
 9 collectively referred to as "Defendants"), acting on behalf of themselves and/or their predecessor  
 10 and/or successor corporations, collected, harvested and/or processed human plasma and/or  
 11 manufactured, marketed, sold and distributed factor concentrate products that were contaminated  
 12 with HCV. In the alternative, one or more of said Defendants participated in the collection,  
 13 harvesting and/or processing of human plasma, and/or the manufacturing, marketing, distribution  
 14 and sale of factor concentrate products, that were contaminated with HCV; or assumed or became  
 15 responsible for, the liabilities of the Defendants and their predecessor or successor corporations  
 16 who did participate in the collection, harvesting and/or processing of human plasma, and/or the  
 17 manufacturing, marketing, distribution or sale of factor concentrate products, that were  
 18 contaminated with HCV, without limitation thereto.

19           16. At all times herein mentioned, Defendants were fully informed of the  
 20 actions of their agents and employees, and thereafter no officer, director or managing agent of  
 21 Defendants repudiated those actions, which failure to repudiate constituted adoption and approval  
 22 of said actions, and Defendants thereby ratified those actions.

#### 23 **IV. FACTUAL ALLEGATIONS**

##### 24 **A. Hemophilia and Its Treatment**

25           17. Hemophilia is an inherited condition that causes uncontrolled  
 26 hemorrhaging or bleeding. Hemophilia results from a deficiency of blood components essential  
 27 for coagulation. The most common form of the disease is hemophilia A, characterized by a lack  
 28 of a blood protein known as Factor VIII, which affects approximately one in 10,000 males.



Factor VIII is commonly called "AHF" or anti-hemophilic factor. Hemophilia B is characterized by absence of another blood protein, known as Factor IX, affecting about one in 40,000 males. Plaintiff LANCE T. RICE has severe hemophilia A.

18. The treatment of hemophilia involves intravenous introduction, called infusion, of the missing blood proteins required to stop bleeding. The two most prevalent forms of such treatment are cryoprecipitate and factor concentrates. Factor concentrates are the products made by Defendants in this action. Cryoprecipitate is made by freezing plasma, the fluid component of circulating blood in which various proteins, including Factor VIII and Factor IX, are contained; thawing the frozen plasma; and isolating Factor VIII from the plasma through centrifugal concentration. Cryoprecipitate is an effective therapeutic agent for patients with hemophilia A. Hemophilia B has been effectively treated with the use of fresh frozen plasma containing Factor IX. Cryoprecipitate and fresh frozen plasma are made from small numbers of donors, who are generally unpaid volunteers.

19. In the late 1960s to early 1970s, Defendants began to market factor concentrates, which contained Factor VIII and Factor IX in higher concentrations than had been available in either cryoprecipitate or fresh-frozen plasma. To produce factor concentrates, Defendants mixed pools of plasma from five to over twenty thousand donors at a time, a large percentage of which were paid donors. These large pools were then subjected to processes to concentrate Factors VIII and IX.

**B. Defendants Failed to Disclose or Warn of Serious Adverse Effects Associated with Factor Concentrates**

20. Shortly after the initial commercial marketing of Factor VIII and IX concentrates in the late 1960s to early 1970s, a wide range of serious adverse effects were reported in association with these products. By that time, Defendants knew of serious diseases caused by unidentified agents transmissible by blood and Factor VIII and IX. Defendants failed to warn Plaintiff or the medical community of these adverse effects, violating industry standards and federal regulations.

1           21. By 1976, only a few years after Defendants' factor concentrate products  
2 went on the market, the United States Food and Drug Administration ("FDA") Bureau of  
3 Biologics held a conference titled *Unsolved Therapeutic Problems in Hemophilia*. The research  
4 articles compiled from the conference discussed the high incidence of disorders in patients using  
5 Defendants' products, such as liver dysfunction, enlarged spleen, Hepatitis B, and Non-A, Non-B  
6 Hepatitis ("NANB Hepatitis," later renamed Hepatitis C). The articles concluded that these  
7 disorders were tied to the patients' use of factor concentrates, and emphasized the risks entailed in  
8 producing such concentrates using plasma from paid donors. For instance, Robert Gerety of the  
9 FDA Bureau of Biologics, Division of Blood and Blood Products, reported that the agent or  
10 agents of NANB Hepatitis "appear to be blood borne, perhaps to be associated with a form of  
11 chronic hepatitis, and to represent a considerable risk to recipients who repeatedly require the  
12 administration of blood products." Gerety, et al., *Viral Antigens and Antibodies in People with*  
13 *Hemophilia* (1977). Gerety noted that "[t]he use of large plasma pools from paid donors no  
14 doubt contributes to the risk of HBV [Hepatitis B] infection from these products," and stated that  
15 "an all voluntary blood donor system is being pursued as a result of the known increased risk of  
16 PTH [post-transfusion hepatitis] from blood derived from commercial donors." As described  
17 below, however, Defendants not only refused to implement such a voluntary donor system, but  
18 instead recruited paid donors precisely because their hepatitis exposure resulted in plasma from  
19 which Defendants could make other commercially valuable products as well.

20           22. At all times material to this Complaint, Defendants failed to adequately  
21 warn Plaintiff or his physicians of the serious adverse side effects of their products. Although  
22 Defendants' package inserts mentioned a risk that plasma "may" contain the causative agent of  
23 viral hepatitis, this warning was seriously deficient in that: (a) Defendants failed to disclose that  
24 the risk of hepatitis was essentially a 100% guarantee due to their practices of using high-risk  
25 donors and specifically recruiting for donors who had previously been exposed to Hepatitis B; (b)  
26 while "hepatitis" simply means inflammation of the liver, and may be a relatively benign,  
27 temporary condition, Defendants failed to warn that some forms of hepatitis transmitted by their  
28 products were believed to present a considerable risk of severe liver damage and a significantly



1 elevated risk of liver cancer; (c) Defendants misleadingly stated that the source plasma used in  
2 preparation of their products had been found to be non-reactive for Hepatitis B surface antigen  
3 (HBsAg)—implying that no viral hepatitis was present in the plasma—and falsely stated that  
4 available methods were not sensitive enough to detect all units of potentially infectious plasma,  
5 failing to disclose that in fact Defendants had refused to implement the more sophisticated  
6 Hepatitis B Core antibody (HBc) test which would have excluded the majority of plasma  
7 contaminated by hepatitis; and (d) Defendants' labeling disclosed that their products were made  
8 from large pools of fresh human plasma, but failed to disclose that paid donors increased the risk  
9 of disease, and that the particular groups of paid donors targeted by Defendants were known to be  
10 the highest risk groups.

11           23. The demand for and supply of anti-hemophilic factor rapidly increased  
12 during the 1970s, with commercially-manufactured concentrate accounting for a large proportion  
13 of the increase in supply. In 1977, a federal report projected that the volume of factor  
14 concentrates manufactured would increase substantially by 1980. Division of Blood Diseases and  
15 Resources, National Heart, Lung and Blood Institute, *Study to Evaluate the Supply-Demand*  
16 *Relationships for AHF and PTC Through 1980*, at page 8; hereinafter "NHLBI Report."

17           24. In order to sell more factor concentrates to this growing market,  
18 Defendants turned to the fastest and cheapest way of obtaining sufficient plasma, paid donors.  
19 Defendants recruited paid donors from those populations most likely to respond to the financial  
20 incentive to donate: poor inner city residents, drug abusers, prisoners, and residents of  
21 impoverished developing countries such as Haiti and Nicaragua.

22           25. Defendants purposefully sought out paid donors despite knowing that the  
23 risk of diseases transmissible by blood was far greater among paid donors than among volunteers.  
24 Because no test was yet available in the 1970s for the NANB Hepatitis virus, an essential means  
25 to prevent the virus from contaminating the plasma supply was to exclude donors with behaviors  
26 that were inconsistent with good health—precisely those populations from which Defendants  
27 were recruiting paid donors. Some studies indicated that paid donors were up to ten times more  
28 infectious than volunteer donors. For this reason, the National Blood Policy, adopted by the

1 federal government in July 1973, advocated conversion to an all-volunteer blood supply.

2 Defendants, however, not only continued to use paid donors, but also focused their recruiting  
3 efforts on the highest risk populations.

4           26. Defendants had an additional financial incentive for recruiting paid donors.  
5 Factor VIII and Factor IX are only two of many products that can be made for commercial sale  
6 from human plasma. According to the NHLBI Report, by the late 1970s at least 17 different  
7 therapeutic components of blood were manufactured by the process of "fractionating" plasma into  
8 its various elements. The NHLBI Report noted that, "as the costs of fractionation have increased,  
9 fractionators have produced as many products as possible from a liter of plasma." *Id.* at 65.

10           27. Blood derivatives used as vaccines or therapeutics had particularly high  
11 economic value for Defendants. The NHLBI Report noted that plasma with a very high titer, or  
12 antibody level, for a corresponding antigen is "very expensive." *Id.* at 41. Such products are  
13 manufactured from source plasma drawn from donors who have been sensitized to a particular  
14 antigen. *Id.* The NHLBI Report specifically stated, however, that "plasma collected for high  
15 antibody titer **cannot** be used for fractionation into therapeutic products," such as Defendants'  
16 factor concentrate. *Id.* (emphasis added).

17           28. Defendants targeted donors with high titers to Hepatitis B antigens in order  
18 to manufacture and sell Hepatitis B immunoglobulin (HBIG), a product that confers temporary  
19 immunity to the Hepatitis B virus. Despite the warning in the NHLBI report, Defendants used the  
20 same high-titer plasma obtained for making HBIG to manufacture their Factor VIII and IX  
21 products used by people with hemophilia. Defendants thus sought to maximize profits by  
22 producing "as many products as possible from a liter of plasma," while ignoring industry  
23 standards that precluded the use of high-titer plasma for other therapeutic products.

24           29. Beginning in about 1978, Defendants began targeting homosexual donors  
25 in known urban gay communities. Because urban homosexuals had been reported in the 1970s to  
26 have exceptionally high prevalence of Hepatitis B infection, Defendants knew that such donors  
27 would provide a reliable source of plasma for the manufacture of commercially valuable HBIG.  
28



1           30. By the 1970s, it was also well-known in the public health community that  
2 urban homosexuals engaged in promiscuous sexual practices that rapidly transmitted other  
3 diseases, including NANB Hepatitis, which were transmitted by blood and were believed to have  
4 serious adverse consequences. Despite this knowledge, Defendants used the same plasma pool  
5 from urban homosexuals to manufacture both HBIG and Factor VIII and IX.

6           31. By the 1970s, it was also well-established that plasma from prison  
7 populations carried a high risk of hepatitis and other blood-borne diseases, primarily because of  
8 the concentration of intravenous (IV) drug users in prisons. By 1974, the alanine  
9 aminotransferase ("ALT") test was available to test for elevated levels of liver enzymes called  
10 SGOT that indicate the presence of hepatitis. Prisoners were associated with SGOT levels of  
11 over 60 IUs per ml, a level that increases the risk of Hepatitis C transmission by a factor of 6.  
12 Despite knowledge of this risk, Defendants actively recruited prisoners for plasma used to  
13 manufacture Factor VIII and IX, while concealing or failing to disclose the risk to Plaintiff, his  
14 physicians, or the FDA.

15           32. In light of Defendants' special knowledge of the disease patterns among  
16 urban homosexuals and prisoners, and their recruitment of such donors for Factor VIII and IX  
17 manufacture, Defendants had duties to: (a) discontinue the practice of using such high risk  
18 donors; (b) disclose the risk to Plaintiff, his physicians, and the FDA, including the ongoing risk  
19 of continuing to use Factor VIII and IX previously manufactured with high risk plasma and still  
20 marketed to patients; (c) implement procedures to kill blood-borne diseases in the products; and  
21 (d) recall existing products from distribution or further use. Instead, Defendants continued to  
22 conceal their recruitment of high-risk donors and to resist warnings and recalls, and failed to  
23 implement procedures to make their products safe.

24           33. By no later than 1978, Defendants knew of the availability of a new test to  
25 determine whether an individual had a history of viral hepatitis, which would have disqualified  
26 the donor from providing plasma for the manufacture of Factor VIII or IX. By testing a person's  
27 serum for the presence of the core to the Hepatitis B antibody, a history of viral hepatitis could be  
28 verified. This was known as the "HBc test." Published, peer-reviewed literature shows that the

1 HBe test was in use by researchers to determine that homosexual AIDS victims had a history of  
2 viral hepatitis by no later than December 1981. Gottlieb, et al., *Pneumocystis Carinii Pneumonia*  
3 *and Mucosal Candidiasis in Previously Healthy Homosexual Men*, 305 New Eng. J. Med. 1425-  
4 1431 (1981).

5 34. Use of the HBe test would have eliminated approximately 75% of  
6 homosexual plasma donors and over 90% of promiscuous urban homosexuals. It would have  
7 eliminated almost 100% of intravenous drug users.

8 35. Use of the HBe and ALT tests together by Defendants by 1981 would have  
9 eliminated the vast majority of the transmitters of HCV from the blood and plasma pools of the  
10 nation, before the height of the Hepatitis C epidemic. If Defendants had implemented this test in  
11 a timely manner, Plaintiff more likely than not would not have been infected with HCV as a result  
12 of factor concentrate use.

13 36. As noted below, federal regulations required plasma donors to be in good  
14 health, and donors with a "history of viral hepatitis" were by definition unacceptable as blood or  
15 blood plasma donors. Persons with a history of viral hepatitis were excluded not only because of  
16 the risk of transmitting Hepatitis B, but because such a history indicated a lifestyle or previous  
17 behavior of the prospective donor that carried the risk of transmitting other viruses in addition to  
18 hepatitis. A reasonable and prudent plasma fractionator would not accept a HBe positive donor  
19 and expect to be in compliance with federal regulations as of 1978.

20 37. After public reports of the first hemophilia AIDS cases in July 1982,  
21 government officials urged Defendants to implement the HBe test as a "surrogate" or "marker" to  
22 eliminate plasma contaminated by the transmitter of AIDS and Hepatitis C. HBe testing was also  
23 strongly suggested to Defendants by the CDC at a meeting of the United States Public Health  
24 Service ("PHS") on January 4, 1983. Despite this urging, Defendants continued to use  
25 contaminated plasma donations that would have been excluded by the HBe test and continued to  
26 conceal from Plaintiff, his physicians, and the FDA the dangerous practice of targeting donors at  
27 highest risk for hepatitis. At a January 6, 1983 meeting of Defendants' trade association, the  
28 Pharmaceutical Manufacturer's Association, Defendants agreed not to implement the highly



1 effective HBc donor screening, and instead opted to use ineffective donor questionnaires that did  
2 little to screen out donors at high-risk for Hepatitis C transmission.

3 38. As late as December 13, 1983, years after the HBc test was available, a  
4 memorandum from CUTTER's responsible head, Stephen Ojala, reporting back on a meeting  
5 held by Defendants, shows that Defendants conspired to propose a "task force" to further study  
6 the use of HBc as an intentional, bad faith "delaying tactic for the implementation" of the test.

7 C. Defendants Also Declined to Implement Available Treatment With Solvents  
8 and/or Detergents to Kill Blood-Borne Diseases, and Continued to Dump  
9 Contaminated Product on the Market After Safer Product Was Available

10 39. In the late 1970s and early 1980s, it was recognized that viruses were in all  
11 factor concentrate products. Treatment with solvents and/or detergents was available at that time  
12 to eliminate many of these viruses, including HCV. Defendants were required to take reasonable  
13 steps to eliminate contamination, but Defendants failed to utilize these available technologies to  
14 eliminate the viruses in a timely manner.

15 40. Solvent and/or detergent treatment was available to Defendants by the late  
16 1970s as a simple and effective method of eliminating viruses in factor concentrate products.  
17 Solvents and/or detergents effectively kill viruses such as HCV by destroying the viruses' lipid  
18 envelope. This method is simpler than heat treatment, and unlike heat treatment does not  
19 interfere with the Factor VIII and IX proteins needed for blood clotting.

20 41. Solvents and/or detergents were well-known, commercially available  
21 products as of the 1970s, and studies in which solvent and/or detergent treatment was used to  
22 disrupt viruses were published in the 1970s in peer-reviewed journals. In 1980, Dr. Edward  
23 Shanbrom, a former Baxter scientist, received a patent for a detergent treatment process for viral  
24 inactivation of factor concentrate. Dr. Shanbrom describes the implementation of this process as  
25 "as easy as washing your hands."

26 42. After receiving the patent, Dr. Shanbrom approached Defendants about  
27 implementing his method, but Defendants refused to heed Dr. Shanbrom's advice. Defendants  
28 refused to even commit any resources to investigate the solvent and/or detergent method.

1           43. Defendants were notified of the successful use of organic solvents to  
2 destroy lipid viruses, including NANB, in factor concentrates by the New York Blood Center  
3 ("NYBC") at the National Hemophilia Federation's meeting on October 27, 1983.

4           44. In 1984, Dr. Prince and Dr. Horowitz of the NYBC published the results of  
5 their successful use of the solvent detergent process in well-known medical journals. They  
6 offered to license the process to Defendants for a reasonable fee. In 1985, the NYBC obtained a  
7 license from the FDA to market a solvent detergent inactivated factor concentrate.

8           45. By March, 1984, Defendants obtained licenses to sell Factor VIII treated  
9 with dry heat to inactivate viruses, and Defendants had obtained such licenses for Factor IX by  
10 October, 1984. The FDA did not allow them to label these products as hepatitis safe. By fall of  
11 1984, Defendants were notified by treaters that previously-untreated patients in their clinical trials  
12 using their dry heated products developed elevated ALT enzymes, indicative of NANB  
13 infections.

14           46. Defendants were therefore aware in 1984 that dry heat did not effectively  
15 inactivate the virus that causes HCV, and that solvent detergent treatment methods did eliminate  
16 the risk of HCV infection, but chose not to employ the effective and efficient solvent detergent  
17 technology. Instead, Defendants continued to sell their contaminated dry heat product for at least  
18 four more years, resulting in the needless infection of Plaintiff and many other hemophiliacs.

19           47. A recent CDC study documented the comparative effectiveness of the dry  
20 heat and solvent detergent inactivation methods. The study reported that "84% of previously  
21 untreated patients infused with dry-heated Factor VIII products developed non-A, non B  
22 hepatitis..." Soucie, Richardson, Evatt et al., *Risk Factor for Infection with HBV and HCV in a*  
23 *Large Cohort of Hemophilic Males*, 41 *Transfusion* 338-343 (2001).

24           48. The same CDC study reported that "solvent detergent treatment of blood  
25 components [was] found to be more effective against enveloped viruses than heat treatment ...  
26 No cases of HBV, HCV, or HIV transmission through solvent detergent virus inactivated  
27 products have been found in prospective studies of previously untreated patients..."  
28

1           49. The study further reported "in our data, the first dramatic decline in HCV  
2 prevalence appears in the 1987 birth cohort. The drop in HCV transmission correlates with the  
3 licensing of solvent detergent treatment of Factor IX products in 1987. In addition, this cohort  
4 would have been the first to benefit from the screening of blood donors using the surrogate  
5 markers ALT (begun in late 1986) and anti-HBc (begun in 1987), testing that was associated with  
6 a markedly decreased risk of HCV infection from blood transfusions."

7           50. The study states further that "the residual transmissions after 1987 possibly  
8 represent the use of product already manufactured or product manufactured during the interval  
9 required to implement the new technology. The 18-month shelf life of factor concentrates placed  
10 those people with hemophilia born as late as 1989 at risk of infection." The study goes on to  
11 recommend testing for all people with hemophilia who received infusions of Defendants' blood  
12 products prior to 1992.

13           51. By 1988, it was clear to the medical and scientific community what  
14 Defendants had long known: dry-heated factor concentrates were transmitting the potentially  
15 deadly NANB virus, and safer products were available. This knowledge prompted the CDC to  
16 publish recommendations that dry-heated products no longer be used by hemophiliacs.  
17 Defendants continued sales of their dry-heated products after these warnings, however, and never  
18 undertook a large-scale recall of dry-heated product. Defendants finally introduced solvent  
19 detergent-treated products to the market in 1988 and 1989, but continued to sell their NANB-  
20 contaminated dry-heated factor concentrates after this date.

21           52. The failure of Defendants to implement solvent and/or detergent viral  
22 inactivation techniques in a timely manner, to warn of the risk that dry heat treated Factor VIII  
23 and IX blood products could transmit HCV, and to recall dry heat-treated products that posed this  
24 risk caused the needless infection of thousands of people with hemophilia with HCV, including  
25 Plaintiff. Even after Defendants knew or should have known that solvent and/or detergents  
26 effectively destroyed HCV, they continued to sell dry heat-treated Factor VIII and IX, and  
27 refused to recall these dangerous products from the market.  
28



1           D.   Defendants Fraudulently Misrepresented the Safety, and Concealed the  
 2           Dangers, of Their Factor VIII and IX Products

3           53.   Defendants engaged in a pattern and practice of fraudulent concealment of  
 4           their dangerous practices, fraudulent misrepresentations regarding their efforts to assure safety,  
 5           and fraudulent misrepresentations regarding the risk of Hepatitis C, in order to maintain profits  
 6           from both factor concentrates and HBIG. A summary of Defendants' fraudulent  
 7           misrepresentations and concealment is set forth below.

8           54.   On July 27, 1982, a meeting of the Public Health Service was held as the  
 9           result of the CDC's report that three people with hemophilia had contracted AIDS. The  
 10          responsible heads of Defendants were in attendance, along with officials from the National  
 11          Hemophilia Foundation, CDC and FDA. Defendants were aware that they had used plasma from  
 12          known, targeted homosexuals in the manufacture of their Factor VIII and IX blood products.  
 13          These products had a shelf life of two years and were either in production or already on the  
 14          shelves in pharmacies waiting to be infused by people with hemophilia who purchased them.  
 15          Defendants failed to disclose these facts at the meeting where CDC officials were present, despite  
 16          knowledge that the CDC's primary concern at that meeting was the contamination of Factor VIII  
 17          and IX by the agent that transmitted AIDS, which, like hepatitis, was already well-known to be  
 18          epidemic in the targeted homosexual population. (CUTTER memorandum dated August 3,  
 19          1982.)

20          55.   In or about December, 1982, Rodell, the responsible head for BAXTER,  
 21          entered into an agreement with officials of the FDA to the effect that BAXTER would no longer  
 22          use prison plasma in the production of factor concentrates. In fact, BAXTER, unbeknownst to  
 23          the FDA, continued to use prison plasma in factor concentrate production through October 1983.  
 24          BAXTER memorandum dated October 20, 1983.

25          56.   On January 5, 1983, an AIDS meeting was held at Children's Orthopedic  
 26          Hospital in Los Angeles, California, the largest hemophilia treatment center in the United States.  
 27          Representatives of Defendants were present at the meeting with treaters and patients. A patient  
 28          asked representatives from Defendants the following question: "Is the plasma from homosexuals,

1 prisoners, Haitians or other high risk persons being used in the manufacture of concentrates?"  
 2 Defendants did not admit targeting or using plasma from homosexuals, prisoners or inner city IV  
 3 drug abusers. Defendants' representatives made no response to the question, thereby concealing  
 4 the true risk created by the use of plasma from known homosexuals, IV drug abusers and  
 5 prisoners in the manufacture of factor concentrates.

6 57. At the January 5, 1983 meeting, and in the presence of the patients, one of  
 7 the treating physicians, Dr. Kasper, asked CUTTER's Stephen Ojala: "These [plasma] centers  
 8 seem to be in rundown centers of town. Is there a move to move them to rural towns?" Ojala  
 9 answered: "Many of the centers are in smaller communities and in towns such as Ypsilanti,  
 10 Seattle, Clayton, NC., and San Diego. We do not have centers in L.A. or San Francisco." This  
 11 answer was misleading because Ojala failed to state that CUTTER's largest and first plasma  
 12 center was located at Arizona State Penitentiary. CUTTER also had a center at the Las Vegas  
 13 Prison. Ojala and CUTTER were well aware of the CDC's and FDA's concern over use of prison  
 14 plasma, due to homosexual practices and drug abuse in the prison donor population. Many of  
 15 CUTTER'S centers were in inner city areas frequented by IV drug abusers, such as downtown  
 16 Oakland, California. CUTTER had also used plasma from centers which targeted known  
 17 homosexuals. In August 1982, CUTTER quarantined plasma from the Valley Medical Center, a  
 18 center which targeted known homosexuals, because a donor was hospitalized with full blown  
 19 AIDS. The plasma was intended for factor concentrate and HBIG production, but was not used  
 20 because it had thawed on the way to the processing plant. Upon receiving a report of this incident  
 21 from CUTTER, the FDA indicated a recall might have been necessary if the plasma had been  
 22 incorporated into factor concentrate final product. Ojala omitted any mention of these facts and  
 23 circumstances in his response to Dr. Kasper regarding the location of their plasma centers.  
 24 (CUTTER memorandum dated January 5, 1983.)

25 58. On January 14, 1983, responsible heads from Defendants attended a  
 26 meeting of the National Hemophilia Foundation ("NHF"). Defendants were very concerned that  
 27 the NHF would insist on a recommendation that HBc testing be implemented, consistent with the  
 28 CDC recommendation 10 days earlier. In order to defer a NHF recommendation that HBc testing

1 be used, Michael Rodell, a representative of BAXTER, told NHF officials on behalf of  
2 Defendants, that surrogate testing was in the "R and D," or "Research and Development," stage  
3 currently. Rodell concealed the fact that the CDC had strongly recommended use of the HBc  
4 antibody test as a screening device for high risk donors. The HBc antibody test was not in the "R  
5 and D" stage, and was suitable for use as a screening device for high risk AIDS and Hepatitis C  
6 donors. In fact, the HBc test had been approved in 1979 by the FDA as a test to be used to  
7 ascertain a history of previous hepatitis B infection, and to screen blood and plasma donors.  
8 Donors with a hepatitis history were specifically prohibited pursuant to the federal regulations (21  
9 C.F.R. § 640.63). Rodell acknowledged that implementation of the HBc test would eliminate  
10 high titered immunoglobulin donors, but failed to disclose that opposition to use of the test was  
11 based on economic rather than safety concerns.

12 59. At the January 14, 1983 meeting, Defendants concealed their advertising in  
13 publications distributed among urban homosexuals, for the specific purpose of attracting them to  
14 plasma centers which supplied high titered plasma to Defendants. Defendants also concealed  
15 their extensive use of prison plasma, and failed to reveal their "gentlemen's agreement" with the  
16 FDA to discontinue use of these plasma sources immediately. (CUTTER Memorandum dated  
17 January 17, 1983.)

18 60. On or about December 15, 1983, Rodell, then the head of Armour  
19 Pharmaceutical Company, Inc., told members of the federal Blood Product Advisory Committee  
20 (BPAC) and FDA officials that Defendants wanted a three-month deferral in implementation of  
21 any recommendations by the BPAC or FDA that HBc testing be required for plasma donors.  
22 Rodell told the FDA that the purpose of the deferral was to prepare a response to the proposed  
23 recommendation. In fact, Defendants had agreed to seek the three-month hiatus as a "delaying  
24 tactic" to avoid implementing the test, and the request for a deferral was made in bad faith.  
25 (CUTTER memorandum dated December 13, 1983.)

26 61. Defendants fraudulently misrepresented the risk of Hepatitis C due to  
27 factor concentrates, failed to disclose accurate warnings of the risk to Plaintiff or his physicians,  
28 and fraudulently purported to be doing "everything possible" to improve safety, when in fact



Defendants maximized the risk by recruiting high-risk donors and by resisting and obstructing HBe testing, treatment with solvents and/or detergents, and other measures that would truly have reduced the risk.

**E. Defendants' Activities Were Subject to Applicable Federal Regulations, Which Evidence the Standard of Care With Which Defendants Should Have Complied**

62. Blood derivatives such as Factor VIII and IX are prescription biologicals subject to federal regulation as both "biological products" and "drugs." Public Health Service Act, "Regulation of Biological Products," 42 U.S.C. § 262; Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.* (2005).

(a) 21 U.S.C. § 331(b) prohibited and continues to prohibit "adulteration or misbranding of any ... drug . . . ."

(b) 21 U.S.C. § 351(a)(2)(B) provided and continues to provide that "[a] drug . . . shall be deemed to be adulterated . . . if . . . the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety. . . ."

(c) 21 U.S.C. § 352 provided and continues to provide that "[a] drug... shall be deemed to be misbranded. .. if its labeling is false or misleading in any particular."

(d) 21 U.S.C. § 352(f)(2) provided and continues to provide that a drug shall be deemed to be "misbranded" unless its labeling bears "adequate warnings against use. .. where its use may be dangerous to health."

(e) 21 U.S.C. § 352(n) provided and continues to provide that a drug shall be deemed to be "misbranded" unless the labeling included information concerning side effects and contraindications as required in federal regulations.

(f) 21 U.S.C. § 321(n) provided and continues to provide that if an article is alleged to be misbranded because the labeling or advertising is misleading, then the determination of whether the labeling or advertising is misleading shall take into account "not only representations made or suggested" by affirmative statements, "but also the extent to which

1 the labeling or advertising fails to reveal facts material in the light of such representations or  
 2 material with respect to consequences which may result from the use" of the drug.

3 63. At all times material to this Complaint, 21 C.F.R. § 201.57(e) provided and  
 4 continues to provide as follows, with respect to information to be provided with the sale of  
 5 Defendants' products:

6 Warnings: Under this section heading, the labeling shall describe  
 7 serious adverse reactions and potential safety hazards, limitations in  
 8 use imposed by them, and steps that should be taken if they occur.  
 9 The labeling shall be revised to include a warning as soon as there  
 10 is reasonable evidence of an association with a drug; a causal  
 11 relationship need not have been proved.

12 64. At all times material to this Complaint, 21 C.F.R. § 200.5 provided and  
 13 continues to provide as follows:

14 Manufacturers and distributors of drugs and the Food and Drug  
 15 Administration occasionally are required to mail important  
 16 information about drugs to physicians and others responsible for  
 17 patient care. In the public interest, such mail shall be distinctive in  
 18 appearance so that it will be promptly recognized and read.

19 65. At all times material to this Complaint, Part 606 of 21 C.F.R. set forth and  
 20 continues to set forth "Current Good Manufacturing Practices" for biological products generally,  
 21 and 21 C.F.R. § 640, *et seq.*, set forth additional good manufacturing practices for blood and  
 22 plasma biologicals.

23 66. At all times material to this Complaint, 21 C.F.R. § 606.140(a) provided  
 24 and continues to provide:

25 Laboratory control procedures shall include: The establishment of  
 26 scientifically sound and appropriate specifications, standards and  
 27 test procedures to assure that blood and blood components are safe,  
 28 pure, potent and effective.

67. At all times material to this Complaint, 21 C.F.R. § 640.60 defined and  
 continues to define "Source Plasma" as:

the fluid portion of human blood collected by plasmapheresis, and  
 is intended as source material for further manufacturing use.

68. At all times material to this Complaint, 21 C.F.R. § 640.63(c), (1999), titled "Qualification of Donor," provided and continues to provide as follows with respect to donors of source plasma:

Donors shall be in good health on the day of donation, as indicated in part by: . . . (9) freedom from any disease, other than malaria, transmissible by blood transfusion, in so far as can be determined by history and examination indicated in this section; (10) freedom of the arms and forearms from skin punctures or scars indicative of addiction to self-injected narcotics; (11) freedom from a history of viral hepatitis; (12) freedom from a history of close contact within six months of donation with an individual having viral hepatitis; . . .

Further, 21 C.F.R. § 640.63(a) provided and continues to provide that the method of determining "suitability of a donor" included "tests" as well as the taking of a history and physical examination.

69. The foregoing statutes and regulations are evidence of the standard of care Defendants should have employed in the manufacture and sale of Factor VIII and Factor IX. Defendants violated the foregoing regulations and/or failed to comply with applicable standards of care by: (a) marketing "adulterated" products that were unsafe as a result of failure to comply with "Current Good Manufacturing Practice"; (b) marketing "misbranded" products that were misleading and failed to disclose or warn of health dangers; (c) failing to warn of serious adverse reactions and potential safety hazards as soon as there was reasonable evidence of an association with their products; (d) failing to exclude intravenous drug users who were unsuitable donors; (e) failing to exclude donors with a history of viral hepatitis who were unsuitable donors; (f) affirmatively seeking out unsuitable donors known to have viral hepatitis antibodies, as well as prison populations known to include substantial numbers of intravenous drug users, for inclusion of their plasma in the pools used to make Factor VIII and Factor IX; (g) failing to disclose their use of dangerous donors; and (h) failing to use appropriate tests and/or procedures to assure their products were safe.

#### F. Group Liability

70. All Defendants likely to have caused the harm to Plaintiff are parties to this lawsuit and properly before the court.



1           71. The conduct of Defendants, with respect to their Factor VIII and Factor IX  
2 products and related plasma collection methods, was tortious.

3           72. The harm which has been caused to Plaintiff resulted from the conduct of  
4 one, or various combinations of the Defendants, and, through no fault of Plaintiff, there may be  
5 uncertainty as to which one or combination of Defendants caused the harm.

6           73. The burden of proof should be upon each Defendant to prove that the  
7 Defendant has not caused the harms suffered by the Plaintiff.

8           74. Factor concentrates were manufactured using the same fractionation  
9 method by all Defendants. As such, during the relevant years, factor concentrates were a fungible  
10 product, and physicians prescribed the products interchangeably without regards to brand names.

11           75. The factor concentrates manufactured by Defendants contained the same  
12 design flaws. They were all manufactured from paid donor plasma, which was at highest risk for  
13 Hepatitis B and Hepatitis C viral transmission. In addition, all Defendants' factor concentrates  
14 were made from large pools consisting of 5,000 to over 20,000 paid donors, which further  
15 magnified the risk of viral transmission.

16           76. None of the factor concentrates made by Defendants during the relevant  
17 time period were subjected to viral inactivation processes such as solvent and/or detergent  
18 treatment that were effective against HCV. Therefore, all of Defendants' factor concentrates  
19 carried a significant risk of HCV transmission during this time. In addition, all of Defendants'  
20 factor concentrate products were similarly misbranded. All of the products failed to warn of the  
21 known risks enumerated in this complaint.

22 **V. TOLLING OF APPLICABLE STATUTES OF LIMITATION**

23           77. Any and all potentially applicable statutes of limitations have been tolled  
24 by Defendants' affirmative and intentional acts of fraudulent conduct, concealment, and  
25 misrepresentation, alleged above, which estop Defendants from asserting statutes of limitation.  
26 Such acts include but are not limited to intentionally covering up and refusing to disclose use of  
27 high-risk plasma; selling products known to be contaminated; suppressing and subverting medical  
28

1 and scientific research; and failing to disclose and suppressing information concerning the risk of  
 2 HCV transmission from Defendants' contaminated factor concentrates.

3 78. Defendants are estopped from relying on any statutes of limitation because  
 4 of their fraudulent concealment and misrepresentation alleged above. Defendants were under a  
 5 duty to disclose the precise risks of HCV transmission from their contaminated factor concentrate  
 6 because this is nonpublic information over which they had exclusive control, because Defendants  
 7 knew this information was not readily available to people with hemophilia like Plaintiff, and  
 8 because this information was relevant to such people in deciding whether to use Defendants'  
 9 factor concentrate.

10 79. Until very recently, Plaintiff had no knowledge that Defendants were  
 11 engaged in much of the wrongdoing alleged herein. Because of the fraudulent and active  
 12 concealment of the wrongdoing by Defendants, including but not limited to deliberate efforts—  
 13 which continue to this day—to give Plaintiff the materially false impression that Defendants  
 14 undertook all feasible safety precautions to reduce the risk of HCV transmission from their  
 15 contaminated factor concentrates, Plaintiff could not reasonably have discovered the wrongdoing  
 16 any time prior to this time, nor could Plaintiff have, as a practical matter, taken legally effective  
 17 action given the unavailability, until very recently, of internal memoranda and other documents  
 18 (as generally described herein) as evidence in support of Plaintiff's claims. Defendants still  
 19 refuse to admit and continue to conceal their wrongdoing, and therefore Defendants' acts of  
 20 fraudulent concealment and misrepresentation continue through the present time.

## 21 **VI. CLAIMS FOR RELIEF**

### 22 **FIRST CLAIM FOR RELIEF**

#### 23 **FRAUDULENT OMISSION AND CONCEALMENT**

24 80. Plaintiff incorporates by reference all previous paragraphs of this  
 25 Complaint as if fully set forth here and further alleges as follows:

26 81. Defendants had a confidential and special relationship with Plaintiff due to:  
 27 (a) Defendants' vastly superior knowledge of the health and safety risks relating to Factor VIII  
 28 and Factor IX; (b) Defendants' sole and/or superior knowledge of their dangerous and

1 irresponsible plasma collection practices; and (c) Defendants' direct communications with the  
 2 hemophiliac community through newsletters that purported to accurately convey the risk of  
 3 NANB. As a result, Defendants had an affirmative duty to fully and adequately warn the  
 4 hemophiliac community, including Plaintiff and physicians, of the true health and safety risks  
 5 related to their Factor VIII and Factor IX blood products and constituent plasma, and a duty to  
 6 disclose their dangerous and irresponsible plasma collection practices. Independent of any  
 7 special relationship of confidence or trust, Defendants had a duty not to conceal the dangers of  
 8 their products to Plaintiff and his physicians.

9           82. Misrepresentations made by Defendants about the health and safety of their  
 10 factor concentrate products independently imposed a duty upon Defendants to fully and  
 11 accurately disclose to the hemophiliac community, including Plaintiff and physicians, the true  
 12 health and safety risks related to Factor VIII and Factor IX and its constituent plasma, and a duty  
 13 to disclose their dangerous and irresponsible plasma collection practices.

14           83. In connection with their Factor VIII and Factor IX products, Defendants  
 15 fraudulently and intentionally concealed important and material health and safety product risk  
 16 information from Plaintiff, the hemophiliac community, and treating physicians, all as alleged in  
 17 this Complaint.

18           84. Any of the following is sufficient to independently establish Defendants'  
 19 liability for fraudulent omission and/or concealment:

- 20           a. Defendants fraudulently concealed the health and safety hazards,  
 21 symptoms, diseases and/or health problems associated with their  
 22 Factor VIII and Factor IX blood products and related plasma collection  
 activities;
- 23           b. Defendants fraudulently concealed the practice of using unsuitable plasma  
 24 from unsuitable donors in the manufacture of their Factor VIII and  
 Factor IX blood products;
- 25           c. Defendants fraudulently concealed their practice of avoiding the use of  
 26 available technology to detect viruses in their Factor VIII and Factor IX  
 blood products and the components thereof;
- 27           d. Defendants fraudulently concealed their practice of avoiding the use of  
 28 available technology to destroy viruses in their Factor VIII and Factor IX  
 blood products and the components thereof; and/or



1  
2 e. Defendants fraudulently concealed information about the known  
3 comparative risks and benefits of the use of their Factor VIII and Factor IX  
4 and the relative benefits and availability of alternate products and therapies.

5 85. Defendants knew that Plaintiff, the hemophiliac community, and  
6 physicians would regard the matters Defendants concealed to be important in determining a  
7 course of treatment, including the decision whether to use their Factor VIII and/or Factor IX  
8 blood products.

9 86. As a direct and proximate result of Defendants' fraudulent concealment  
10 and suppression of material health and safety risks relating to their Factor VIII and Factor IX  
11 blood products and of Defendants' dangerous and irresponsible plasma collection practices,  
12 Plaintiff has suffered and will continue to suffer injury, harm and economic loss. As the direct,  
13 proximate and legal result of the Defendants' fraudulent concealment and suppression of material  
14 health and safety risks relating to their Factor VIII and Factor IX blood products and of  
15 Defendants' dangerous and irresponsible plasma collection practices, Plaintiff has been injured  
16 and has incurred damages, including but not limited to permanent physical injuries to his person,  
17 medical and hospital expenses in the past, past disability, past loss of use of the body, and past  
18 physical and mental pain and suffering; and will incur in the future medical and hospital  
19 expenses, permanent disability, loss of use of the body, physical and mental pain and suffering,  
20 and loss of the enjoyment of life.

21 87. Plaintiff is therefore entitled to damages in an amount to be proven at trial,  
22 together with interest thereon and costs.

23 88. Defendants' conduct, as alleged above, was malicious, intentional and  
24 outrageous and constituted willful and wanton disregard for the rights or safety of others. Such  
25 conduct was directed specifically at Plaintiff and warrants an award of punitive damages.

26 89. Plaintiff is informed and believes that Defendants utilize retention policies  
27 that provide for scheduled destruction of documents and other items, which may result in the  
28 knowing, negligent, or inadvertent destruction of documents, data, and materials relevant and  
necessary to adjudication of this action, including, but not limited to, records identifying batch or

lot numbers of Defendants' products shipped to particular treatment facilities, which may facilitate product tracing. This risk warrants an order from this Court that such evidence (including all documents, data compilations, and tangible things within the meaning of Rule 26 of the Federal Rules of Civil Procedure) be preserved and maintained for use in these proceedings.

## **SECOND CLAIM FOR RELIEF**

### **BREACH OF IMPLIED WARRANTY**

90. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

91. Defendants' factor concentrate products were intentionally designed, manufactured, promoted, distributed and sold to be introduced into the human body.

92. Defendants breached the implied warranties of merchantability and fitness because Defendants' factor concentrate products cannot pass without objection in the trade, are unsafe, are not merchantable, are unfit for their ordinary use when sold, and are not adequately packaged and labeled.

93. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

## **THIRD CLAIM FOR RELIEF**

### **NEGLIGENCE**

94. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

95. Defendants marketed their Factor VIII and/or Factor IX blood products to and for the benefit of Plaintiff, and knew or should have known that Plaintiff would use their Factor VIII and/or Factor IX blood products.

96. Defendants owed Plaintiff duties to exercise reasonable or ordinary care under the circumstances in light of the generally recognized and prevailing best scientific knowledge.

97. Through the conduct described in the foregoing and subsequent paragraphs of this Complaint, Defendants breached their duties to Plaintiff. The following sub-paragraphs

1 summarize Defendants' breaches of duties to Plaintiff and describe categories of acts or  
2 omissions constituting breaches of duties by Defendants. Each and/or any of these acts or  
3 omissions establishes an independent basis for Defendants' liability in negligence:

- 4 a. Failure to exercise reasonable care in producing Factor VIII and Factor IX  
5 blood products that were free of viruses, including the virus that causes  
6 Hepatitis C;
- 7 b. Failure to exercise reasonable care in assuring that only suitable plasma  
8 would be used in manufacturing their Factor VIII and Factor IX blood  
9 products;
- 10 c. Failure to exercise reasonable care in testing plasma used in manufacturing  
11 their Factor VIII and Factor IX blood products for viral contamination;
- 12 d. Failure to exercise reasonable care in recruiting and screening donors of  
13 plasma used in their manufacture of Factor VIII and Factor IX blood  
14 products;
- 15 e. Failure to reasonably employ anti-viral techniques, including solvent  
16 and/or detergent treatment, in the manufacture of their Factor VIII and  
17 Factor IX blood products;
- 18 f. Unreasonable overpromotion of their Factor VIII and Factor IX blood  
19 products;
- 20 g. Understating the relative value of hemophilia treatments that constituted  
21 alternatives to their Factor VIII and Factor IX blood products;
- 22 h. Failure to warn physicians, Plaintiff, and the hemophilia community of the  
23 dangers associated with their Factor VIII and Factor IX blood products  
24 and/or the viruses and foreign bodies contained within the plasma used in  
25 manufacturing their Factor VIII and Factor IX blood products;
- 26 i. Failure to exercise reasonable care by complying with federal regulations  
27 then applicable to plasma collection and the manufacture of Factor VIII  
28 and Factor IX blood products;
- 29 j. Failure to exercise reasonable care in disseminating information about their  
30 methods of manufacturing their Factor VIII and Factor IX blood products  
31 and the risks that were created by said methods; and
- 32 k. Failure to exercise reasonable care in recalling their Factor VIII and  
33 Factor IX blood products.



98. Defendants knew, or should have known, that due to their failure to use reasonable care, Plaintiff and other people with hemophilia would use and did use Defendants' Factor VIII and/or Factor IX products to the detriment of their health, safety and well-being.

99. As the direct, proximate and legal result of the Defendants' negligence, Plaintiff has been injured and has incurred damages, including but not limited to permanent physical injuries to his person, medical and hospital expenses in the past, past disability, past loss of use of the body, and past physical and mental pain and suffering; and will incur in the future medical and hospital expenses, permanent disability, loss of use of the body, physical and mental pain and suffering, and loss of the enjoyment of life.

100. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

101. Defendants' conduct, as alleged above, was malicious, intentional and outrageous, and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiff and warrants an award of punitive damages.

#### **FOURTH CLAIM FOR RELIEF**

##### **NEGLIGENCE PER SE**

102. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

103. Defendants violated applicable federal statutes and regulations relating to prescription drugs. Plaintiff is a person whom these statutes and regulations were meant to protect.

104. Defendants' violation of these statutes or regulations constitutes negligence per se.

105. Defendants' violation of these statutes or regulations was the direct, proximate and legal cause of Plaintiff's injuries and damages. As the direct and legal result of the Defendants' negligence, Plaintiff has been injured and has incurred damages, including but not limited to permanent physical injuries to his person, medical and hospital expenses in the past, past disability, past loss of use of the body, and past physical and mental pain and suffering; and

1 will incur in the future medical and hospital expenses, permanent disability, loss of use of the  
2 body, physical and mental pain and suffering, and loss of the enjoyment of life.

3 106. Plaintiff is therefore entitled to damages in an amount to be proven at trial,  
4 together with interest thereon and costs.

5 107. Defendants' conduct, as alleged above, was malicious, intentional and  
6 outrageous and constituted willful and wanton disregard for the rights or safety of others. Such  
7 conduct was directed specifically at Plaintiff and warrants an award of punitive damages.

8 **VII. PRAYER FOR RELIEF**

9 WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

10 108. For compensatory damages sustained by Plaintiff against Defendants in an  
11 amount to be determined at trial;

12 109. For punitive and exemplary damages according to proof against  
13 Defendants;

14 110. For an award of prejudgment interest, costs, disbursements and reasonable  
15 attorneys' fees;

16 111. For injunctive relief in the form of an order requiring Defendants to  
17 preserve all relevant documents; and

18 112. For such other and further relief as the Court deems equitable or  
19 appropriate under the circumstances.

1  
2  
3 Dated: May 21, 2007  
4

  
Heather A. Foster

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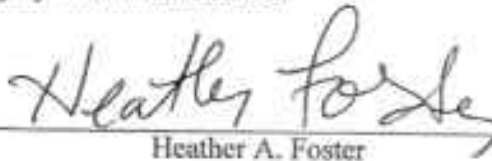
Attorneys for Plaintiffs



**DEMAND FOR JURY TRIAL**

Plaintiff demands a trial by jury on all issues stated.

Dated: May 21, 2007

  
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